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VIA CM-ECF & HAND DELIVERY

The Honorable Richard G. Andrews
United States District Court
J. Caleb Boggs Federal Building
844 N. King Street, Unit 9, Room 6325
Wilmington, Delaware 19801-3555

**Re: *Horizon Medicines LLC v. Alkem Laboratories Ltd.*,
C.A. No. 18-1014-RGA (D. Del.)**

Dear Judge Andrews:

This firm, along with Rakoczy Molino Mazzochi Siwik LLP, represents Defendant Alkem Laboratories Ltd. in the above-referenced action. Pursuant to Your Honor's January 28, 2020 Oral Order (D.I. 120) and the Court's Scheduling Order ¶ 3.f., we respectfully outline herein certain discovery disputes that have arisen between the parties over which they have reached an impasse.

More specifically, Alkem seeks to compel Horizon to (i) present a Rule 30(b)(6) witness to testify concerning (a) the factual bases underlying secondary considerations on which it intends to rely and (b) license agreements relating to the patents-in-suit, DUEXIS®, or Vimovo®, [REDACTED] and (ii) produce any relevant license agreements prior to any deposition. To date, Horizon has refused to produce a witness on secondary considerations or discovery on license agreements, contending that such discovery would be geared towards legal contentions or lacks relevance. However, this discovery is clearly relevant to the claims and defenses asserted, as demonstrated by (i) Horizon's 11th hour disclosure (just prior to its inventor depositions) of secondary considerations on which it intends to rely, thousands of pages of documents in support thereof and the identification of the inventors as persons with knowledge of underlying facts; (ii) Horizon's irreparable harm allegations; and (iii) Horizon's own disclosures concerning [REDACTED]. Horizon's refusal to produce discovery on this subject matter is severely prejudicing Alkem's ability to fully develop its defenses.

I. Background.

In its Complaint, Horizon has alleged that it "will be substantially and irreparably harmed if Defendant is not enjoined from infringing or actively inducing or contributing to the infringement of the" patents-in-suit. (D.I. 1, Compl. ¶¶ 40, 50). Plaintiff also seeks monetary relief in the event Alkem launches its product. (*Id.* at 16 ¶¶ G-H). In response, Alkem has raised various defenses and Counterclaims, including for invalidity. (D.I. 14, Alkem Answer at 21, 28-32).

A. Secondary Considerations.

To develop its defenses, Alkem has timely sought discovery (both written and testimony) from Horizon relating to any secondary considerations on which it intends to rely. In its responses to Alkem's First Set of Interrogatories (served on July 1, 2019), Horizon merely stated that it will

produce documents concerning secondary considerations and reserved “the right to supplement its response to this Interrogatory as discovery continues.” (Ex. 1, Horizon Responses at 4-7). Alkem has repeatedly requested that Horizon disclose any alleged secondary considerations on which it intends to rely. Horizon failed to do so until January 14, 2020, the day just prior to the deposition of inventor George Tidmarsh and just days prior to the depositions of inventors Barry Golombik and Puneet Sharma. At that time, Horizon served supplemental responses to Alkem’s interrogatories and identified for the first time alleged secondary considerations on which it intends to rely (unexpected results, long-felt but unmet need, skepticism and industry praise) in laundry-list fashion and nearly 7,000 pages of documents in support thereof. (*See* Ex. 2, Horizon First Supp. Responses at 4-11). Horizon further disclosed for the first time that the persons “most knowledgeable about the facts underlying the validity of the Patents-in-Suit are the named inventors.” (*Id.* at 9; *see also id.* at 11 (identifying inventors as most knowledgeable concerning unexpected results)).

Despite these disclosures and it having touted the work of its inventors and the “exceptional stability” of the invention, Horizon has refused to produce any Rule 30(b)(6) witness to testify on factual information supporting any alleged secondary considerations, including unexpected properties and long-felt need. (*See* Ex. 3, Horizon 30(b)(6) Responses at 38-40 (Topic Nos. 32-34); Ex. 4, Horizon Claim Construction Presentation at 6, 14, 19; D.I. 1-1, Compl. Ex. A, U.S. Patent No. 8,067,033 at col. 1, ll. 59-62 (discussing “exceptional stability” and how the “invention meets that need”)).

B. License Agreements.

Alkem has further sought production of and testimony concerning license agreements relevant to (i) the patents-in-suit or DUEXIS®; and (ii) any secondary considerations on which Horizon is relying. More specifically, Alkem has sought production of any unredacted settlement/license agreement with generic applicant Par given its relevance to at least Horizon’s irreparable harm allegations.¹ Horizon has rejected all requests, contending that because it is not relying on commercial success, such agreement is not relevant, and that a redacted version of the Par license agreement is available through Horizon’s SEC filings. (*See, e.g.*, Ex. 3 at 7 (Topic No. 2)). However, the redacted version of the agreement omits key information (e.g., profit share) that would be relevant to at least Horizon’s irreparable harm and monetary claims. (*See, e.g.*, Ex. 5, Par License Agreement (public version) at 5-9, Ex. A).

Moreover, based on discovery to date, Alkem has identified at least [REDACTED] that are relevant to Alkem’s invalidity defenses [REDACTED] (See Ex. 6, DX 5 at GFTDXS0015551; Ex. 7, Tidmarsh (rough) at 28, 182-84; Ex. 8, excerpts of [REDACTED] at GFTDXS00000006). Horizon has refused to produce these agreements as well.

* * *

Alkem met and conferred with Horizon concerning Horizon’s failure to provide the requested discovery, including on October 28, 2019, January 10, 2020 and January 16, 2020.

¹ On August 22, 2013, Horizon announced its settlement of litigation involving DUEXIS® with Par. (<https://ir.horizontherapeutics.com/news-releases/news-release-details/horizon-pharma-announces-settlement-duexisr-patent-litigation>), last visited Jan. 30, 2020).

Horizon has maintained its refusal to provide the requested discovery.

II. The Requested Discovery Is Relevant.

Horizon disclosed the secondary considerations on which it intends to rely and nearly 7,000 pages of supporting documents on the eve of the inventor depositions. It has identified the inventors as having knowledge of the underlying facts of its validity position. During the claim construction hearing, Horizon addressed the work of the inventors, including the “[s]imple dosing and [s]table dosage form.” Yet, Horizon continues to reject Alkem’s repeated requests for a Rule 30(b)(6) witness on this subject matter under the guise that such testimony would only be directed to legal contentions. The Court should reject this position. Discovery on secondary considerations is clearly relevant to Alkem’s invalidity defenses and, as Horizon admits through its recent disclosures, fact witnesses will have knowledge of this information. Moreover, Alkem should be allowed to obtain details of the facts underlying Horizon’s theories during fact discovery and not be forced to wait until Horizon introduces its invention story at trial to first have an opportunity to probe Horizon’s challenges to its invalidity defenses.

As for the Par license agreement, such agreements are generally discoverable. *See AbbVie Inc. v. Boehringer Ingelheim Int’l GmbH*, No. 17-cv-01065-MSG-RL, 2019 WL 1571666, at *2 (D. Del. Apr. 11, 2019). The question thus turns to relevance. Horizon’s position that the agreement is not relevant because it is not relying on commercial success wholly ignores that this discovery directly speaks to whether or not Horizon will be irreparably harmed at it contends.² *See Wyeth v. Organon Pharma Inc.*, No. 09-3235 (FLW), 2010 WL 4117157, at *4 (D.N.J. Oct. 19, 2010). Moreover, [REDACTED]

Alkem should be permitted discovery on this issue. Similarly, any agreement with [REDACTED] would be relevant to at least Alkem’s obviousness defense. To this end, based on Horizon’s documents, [REDACTED] Alkem should be allowed to depose a Rule 30(b)(6) witness knowledgeable on the scope of such agreement to permit it to evaluate the scope of rights under the license and what was known concerning [REDACTED] by the priority date.

* * *

Given the current expert discovery deadline of March 6, 2020 (which Alkem wishes to maintain), Alkem respectfully requests that the Court order Horizon to produce (i) a witness or witnesses concerning the facts underlying the secondary considerations on which it relies and any license agreements relating to the patents-in-suit, DUEXIS®, or Vimovo® by February 20, 2020; and (ii) any license agreements relevant to Par and the patents-in-suit, [REDACTED], or Vimovo® at least three (3) days in advance of any deposition.

We enclose a proposed form of Order herein. We thank Your Honor for your attention to this matter.

² Notably, Horizon previously argued it was entitled to certain discovery from Alkem relevant to its claim of irreparable harm. (See Ex. 9, 7/9/19 J. Mackay letter at 3-4).

Respectfully submitted,

/s/ Dominick T. Gattuso
Dominick T. Gattuso (#3630)

DTG/ram

Enclosures

cc: Clerk of the Court (by CM-ECF and Hand Delivery)
Counsel of Record (by CM-ECF and Email)